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(54) Title: IMPLANTABLE MEDICAL ELECTRODE COMPRISING A FLEXIBLE PRINTED CIRCUIT			
(57) Abstract An implantable medical electrode is provided using flexible printed circuit techniques and includes a first insulating layer, a patterned metal layer disposed over the first insulating layer, and a second insulating layer having an aperture. The patterned metal layer includes at least one contact and at least one conductor connected to and extending from the contact. In assembly, the second insulating layer is disposed over the patterned metal layer with the aperture aligned with the contact so as to expose at least a portion of the contact. The patterned metal layer is fabricated using flexible printed circuit techniques.			

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IMPLANTABLE MEDICAL ELECTRODE COMPRISING A FLEXIBLE PRINTED CIRCUIT

CROSS-REFERENCE TO RELATED APPLICATIONS

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Not applicable.

STATEMENTS REGARDING FEDERALLY SPONSORED RESEARCH

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Not applicable.

BACKGROUND OF THE INVENTION

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Implantable medical electrodes are used in a variety of medical applications. One such application is the sensing of cortical electrical activity which can be analyzed to identify the foci of epileptogenic brain for removal. The same implantable medical electrodes which are used to sense cortical electrical activity passively can also be used to stimulate various regions of the brain to further analyze the foci of epileptogenic brain in order to enhance the safety and effectiveness of epileptogenic brain removal.

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One conventional type of implantable medical electrode used for sensing cortical electrical activity is a depth electrode which is a relatively narrow, typically cylindrical structure with conductive ring electrodes spaced along its length. A depth electrode is an intracortical device that is inserted into the brain tissue. Depth electrodes provide electrical contact to, and thus information regarding electrical activity within the brain itself.

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Another type of implantable medical electrode for use in sensing cortical electrical activity is referred to as a strip electrode. A strip electrode is inserted

between the dura and the cortex and does not penetrate the brain. Strip electrodes typically include a flexible, substantially flat strip of dielectric material supporting one or more flat electrical contacts with which cortical electrical activity on the surface of the brain is stimulated and/or sensed. Each flat contact is connected to a proximal end of an insulated lead wire having a distal end suitable for coupling to electrical stimulation and/or monitoring apparatus. It is important that the strip electrode be flexible in order to conform to the patient's cortex.

More particularly, strip electrodes generally include two dielectric layers between which the flat electrical contacts are arranged in a single row. One of the dielectric layers has a plurality of apertures therethrough, with each aperture aligned with a corresponding contact so as to expose at least a portion of the contact.

It is critical that each of the flat contacts comes into contact with the cortex and, once in contact, remains in the same fixed position relative to the cortex. Knowledge of the exact positions of the strip electrode contacts relative to the cortex is necessary in order to properly interpret the electrical readings.

Conventionally, providing a strip electrode with a certain amount of thickness, such as on the order of 0.020 - 0.030 inches, has been felt to maintain adequate positioning of the electrode once implanted. This thickness has also been felt to enhance support of the lead wires by preventing them from breaking away from the contacts and/or becoming dislodged within the strip electrode. However, it is also desirable to make the strip electrode relatively thin, in order to avoid raising intracranial pressure when the dura is closed, particularly in pediatric cases, in which there is only a relatively narrow space between the dura and the brain.

Another type of conventional medical electrode is similar to the strip electrode in construction, but includes an array of electrical contacts and may be referred to as a grid electrode. Thus, such an electrode generally includes two dielectric layers between which a plurality of flat electrical contacts are arranged in the form of a two-

dimensional array with at least a portion of each contact exposed by an aperture in one of the dielectric layers.

5 Because the contacts and insulating lead wires of strip and grid electrodes are quite small (typical insulated lead wire is on the order of 40 gauge wire), manufacture of strip and grid electrodes is labor intensive. Various techniques are possible for electrically connecting the insulated lead wires to the respective contact, including soldering and the use of tabs extending from the contacts for crimping over a stripped end of the wire. The significant labor associated with electrically connecting the
10 conductors to the contacts and precisely placing the contacts in alignment with the apertures of one of the dielectric layers causes such implantable medical electrodes to be relatively expensive. And, since such electrodes are intended for single use, their high cost is significant.

15 **BRIEF SUMMARY OF THE INVENTION**

 The invention is directed to flexible printed circuit structures and techniques for use in providing implantable medical electrodes. Flexible printed circuit techniques
20 permit a thinner than conventional electrode to be provided in a cost effective manner. More particularly, flexible printed circuit techniques are highly repeatable and have a relatively high yield, thereby reducing the manufacturing time and cost associated with providing medical electrodes.

25 In accordance with one embodiment, an implantable medical electrode includes a first insulating layer, a patterned metal layer disposed over the first insulating layer and a second insulating layer having at least one aperture. The patterned metal layer includes at least one contact and at least one conductor connected to and extending from the contact. The second insulating layer is disposed over the patterned metal layer,
30 with the aperture aligned with the contact so as to expose a first portion of the contact and cover a second portion of the contact. An adhesive may be provided between the first and second insulating layers in order to secure the layers together in assembly.

The patterned metal layer may include one or more contacts. In applications in which the electrode includes a plurality of contacts, such contacts may be arranged in various patterns, including a single row or a two-dimensional array. The patterned metal layer may be comprised of any suitable conductive material such as copper, aluminum, platinum, stainless steel, conductive elastomer, and conductive polymer.

Each of the first and second insulating layers is comprised of an electrically insulating, or dielectric material and is flexible in bending, enabling the electrode to conform to the contours of a treatment site. Suitable materials for the first and second insulating layers are known biocompatible polymers, such as silicone, and other materials, such as polyester film (e.g., Mylar) or polyimide film (e.g., Kapton), embedded in a known biocompatible material.

A method of fabricating an implantable medical electrode includes providing a first insulating layer, providing a metal pattern having at least one contact and at least one conductor connected to and extending from the contact, and placing the metal pattern over the first insulating layer. The method further includes providing a second insulating layer having at least one aperture and covering the metal pattern with the second insulating layer so that the aperture is substantially vertically aligned with the contact in order to expose at least a portion of the contact. Preferably, the second insulating layer covers a portion of the contact to maintain the contact in place in assembly. Adhesive may be provided between the first and second insulating layers in order to secure the layers together in assembly.

An alternative method of fabricating an implantable medical electrode includes providing a flexible, insulating substrate, depositing a layer of metal over the substrate and patterning the metal to provide the patterned metal layer with at least one contact and at least one conductor connected to and extending from the contact. Thereafter, a flexible, insulating layer having at least one aperture is provided over the patterned metal layer with the aperture aligned with the contact of the patterned metal layer in order to expose at least a portion of the contact.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing features of this invention, as well as the invention itself, may be more fully understood from the following description of the drawings in which:

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Figure 1 is a cross-sectional view of one embodiment of a medical electrode according to the invention;

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Figure 2 is a plan view of one embodiment of a patterned metal layer suitable for use with the electrode of Figure 1;

Figure 3 is a plan view of an alternative patterned metal layer embodiment suitable for use with the electrode of Figure 1;

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Figure 4 is a cross-sectional view of an alternative embodiment of a medical electrode according to the invention during fabrication;

20

Figure 5 is a cross-sectional view of the electrode of Figure 4 during a further stage of fabrication;

Figure 6 is a cross-sectional view of the electrode of Figure 4 during a still further stage of fabrication; and

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Figure 7 is a cross-sectional view of the electrode of Figure 4 after a final stage of fabrication.

DETAILED DESCRIPTION OF THE INVENTION

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Referring to Figure 1, a medical electrode 10 suitable for being implanted in a patient to contact a treatment site, such as the cortex, is shown. The electrode 10 includes a first insulating layer 14, a second insulating layer 18, and a patterned metal

layer 20 disposed between the first and second insulating layers. The patterned metal layer 20 includes at least one contact 24 and, generally, a plurality of contacts 24a - 24x. The patterned metal layer 20 further includes at least one conductor 28 and, generally, a plurality of conductors 28a - 28x, each electrically connected to and extending from a respective contact 24a - 24x. The second insulating layer 18 has at least one aperture 30 and, generally, a plurality of apertures 30a - 30x therethrough which, in assembly, are substantially vertically aligned with respective contacts 24a - 24x of the patterned metal layer 20.

The diameter of the apertures 30a - 30x in the second insulating layer 18 may be smaller than the diameter of the contacts 24a - 24x so that the layer 18 overlaps a portion of the contacts 24a - 24x to expose a first portion of such contacts and cover a second portion of such contacts. The overlap of the second insulating layer 18 with the contacts serves to hold the contacts in place between the first and second insulating layers in assembly. Alternatively however, the diameter of the apertures 30a - 30x may be larger than the diameter of the contacts so that the second insulating layer 18 does not overlap the contacts. In this embodiment, other means are employed to hold the contacts in place in assembly, such as an adhesive. Regardless of whether or not the second insulating layer 18 overlaps a portion of the contacts 24a - 24x, such insulating layer covers at least a substantial portion, and preferably the entirety of the conductors 28a - 28x.

The patterned metal layer 20 is fabricated using flexible printed circuit techniques as described below. In general, such techniques are highly repeatable and provide a relatively high yield, thereby permitting the patterned metal layer 20 to be provided in a cost effective manner. More particularly, the patterned metal layer 20 includes contacts 24a - 24x and conductors 28a - 28x integrally formed using photolithographic techniques. This arrangement is in contrast to conventional techniques for providing implantable medical electrodes in which the contacts are discrete disk-shaped conductive elements which are, generally, manually connected to conductors for further connection to electrical stimulation and/or sensing apparatus and are further manually and individually placed between the first and second insulating

layers 14, 18, respectively. It will be appreciated by those of ordinary skill in the art that the relatively inexpensive and highly repeatable flexible printed circuit processes used to provide the patterned metal layer 20 significantly reduce the overall cost of the electrode 10 by eliminating not only the time and expense associated with assembling an electrode having discrete contacts and conductors, but also by eliminating a common source of electrode failure which occurs when conductors become dislodged and/or break away from the respective contacts.

The first and second insulating layers 14, 18, respectively, are comprised of a flexible electrically insulating, or dielectric material. More particularly, the insulating layers 14, 18 are flexible in bending to permit the electrode 10 to conform to the contours of a treatment site. The layers 14, 18 may additionally be capable of compression and/or tensile stretching. Suitable dielectric materials for the insulating layers 14, 18 are known biocompatible polymers, such as silicone, and other materials, such as polyester film (e.g., Mylar) or polyimide film (e.g., Kapton), embedded in a known biocompatible material. In applications in which the insulating layers 14 and 18 are comprised of a material capable of compression and/or tensile stretching, such as silicone, the patterned metal layer 20 may be comprised of a similarly compliant material, such as an elastomeric material loaded, or doped with conductive particles.

Various flexible printed circuit manufacturing techniques are suitable for fabricating the patterned metal layer 20. According to one such technique described further below in conjunction with Figures 4 - 7, one of the flexible insulating layers 14 or 18 serves as a substrate on which the patterned metal layer 20 is formed.

In accordance with an alternative flexible printed circuit technique, the patterned metal layer 20 is formed as a separate structure from the insulating layers for assembly between the first and second insulating layers 14, 18, respectively. More particularly, a layer of adhesive is provided on both surfaces of a flexible substrate, such as Kapton. Thereafter, a layer of metal, such as copper, is deposited on both surfaces of the substrate and is etched to provide the contacts and conductors.

The unitary patterned metal layer formed in this manner is provided with a plurality of contacts and a corresponding plurality of conductors which are mechanically, and generally also electrically, interconnected by an interconnecting member. The interconnecting member is provided to facilitate handling of the patterned metal layer. During assembly, the interconnecting member is removed, thereby electrically and mechanically isolating the contacts and conductors of the patterned metal layer.

In the flexible printed circuit process in which the patterned metal layer 20 is formed as a separate structure from the insulating layers, assembly of the electrode 10 includes the steps of positioning the patterned metal layer 20 over the first insulating layer 14 and providing the second insulating layer 18 with the plurality of apertures 30a - 30x therein. The apertures 30a - 30x may be formed by various techniques, such as being punched or die cut. The second insulating layer 18 is positioned over the patterned metal layer 20 such that each of the apertures 30a - 30x is substantially vertically aligned with a corresponding one of the contacts 24a - 24x of the patterned metal layer 20. It will be appreciated by those of ordinary skill in the art that the order of placement of the first and second insulating layers and the patterned metal layer relative to each other can be readily varied. The interconnecting member of the patterned metal layer (Figure 3) is located external to the edges of the first and second insulating layers 14, 18. Once the first and second insulating layers 14, 18 are secured together, the interconnecting member between the conductors 28a - 28x is removed.

In the embodiment of Figure 1, each of the apertures 30a - 30x has a diameter slightly smaller than the diameter of the corresponding contact 24a - 24x, respectively. With this arrangement, a portion of the second insulating layer 18 adjacent to the apertures 30a - 30x contacts an edge portion of the respective contact 24a - 24x, so as to maintain the contact and the entire patterned metal layer 20 in place between the first and second insulating layers in assembly.

An adhesive may be used between the first and second insulating layers 14 and 18, respectively, in order to secure the first and second insulating layers together with

the contacts 24a - 24x and conductors 28a - 28x disposed therebetween. Adhesive may also be used between the patterned metal layer 20 and one or both of the insulating layers 14 and 18 in order to maintain the patterned metal layer in place between the insulating layers, either in addition to the overlap of the second insulating layer 18 with the contacts 24a - 24x or as an alternative to having the second insulating layer 18 overlap such contacts. That is, if other means, such as an adhesive, is used to secure the patterned metal layer 20 in place, then the diameter of the apertures 30a - 30x can be the same as, or greater than the diameter of the contacts 24a - 24x, respectively.

Referring to Figure 2, a plan view of an illustrative patterned metal layer 20' suitable for use in the electrode 10 of Figure 1 includes a plurality of contacts $40_{1,1}$ - $40_{n,m}$ arranged in a two-dimensional array. The patterned metal layer 20' further includes a plurality of conductors $44_{1,1}$ - $44_{n,m}$, each having a proximal end electrically connected to a respective contact $40_{1,1}$ - $40_{n,m}$ and a distal end at which a terminal $48_{1,1}$ - $48_{n,m}$ is provided. The dotted line border of the layer 20' represents edges of the first and second insulating layers 14, 18, in assembly.

Each of the conductors $44_{1,1}$ - $44_{n,m}$ is integrally formed with the respective contact $40_{1,1}$ - $40_{n,m}$ of the patterned metal layer 20' by flexible printed circuit techniques described herein. The conductors $44_{1,1}$ - $44_{n,m}$ extend from the respective contact $40_{1,1}$ - $40_{n,m}$ to an edge 50 of the patterned metal layer 20' and may be formed to extend between the respective contact $40_{1,1}$ - $40_{n,m}$ and the edge along various paths.

The terminals $48_{1,1}$ - $48_{n,m}$ permit electrical connections to be made to the contacts $40_{1,1}$ - $40_{n,m}$ from apparatus external to the patient when the electrode 10 is implanted. Such electrical connections may be achieved in various ways. As one example, the terminals $48_{1,1}$ - $48_{n,m}$ may be disposed adjacent to the edge of insulating layers 14 and 18, either interior or exterior to such edge, for further connection to a wire assembly which extends from the electrode 10. Figure 2 shows one such embodiment in which the terminals $48_{1,1}$ - $48_{n,m}$ are disposed just external to the edge 50 and thus also to the edge of first and second insulating layers 14 and 18 for

electrical connection to individual insulated lead wires $52_{1,1} - 52_{n,m}$ covered by a common insulator 56 which extends out of an incision in the patient.

5 The connection between the insulated lead wires $52_{1,1} - 52_{n,m}$ and the terminals $48_{1,1} - 48_{n,m}$ may be achieved by various techniques, such as soldering. Such insulated lead wires may terminate at a distal end of the insulator 56 in a plurality of ring electrodes $58_{1,1} - 58_{n,m}$, similar to a depth electrode and utilize depth electrode techniques for effecting electrical connection to stimulation and/or sensing apparatus.

10 Referring to Figure 3, an alternate patterned metal layer 20'' includes a plurality of contacts $60_1 - 60_x$, arranged in a single row as in a strip electrode. The dotted line border of the layer 20'' represents edges of the first and second insulating layers 14, 18, in assembly. A plurality of conductors $64_1 - 64_x$ are coupled to respective contacts $60_1 - 60_x$, as shown. More particularly, and like conductors $44_{1,1} - 44_{n,m}$ of Figure 2,
15 each of the conductors $60_1 - 60_x$ has a proximal end electrically connected to and extending from the respective contact $60_1 - 60_x$ and a distal end at which a respective terminal $68_1 - 68_x$ is provided.

20 In the embodiment of Figure 3, the conductors $64_1 - 64_x$ extend from the contacts for some distance, such as on the order of four to five inches, to terminate outside of the patient and permit electrical connection to the respective contacts $60_1 - 60_x$. The terminals $68_1 - 68_x$ at the distal end of the conductors $64_1 - 64_x$ are suitable for making electrical connections to electrical stimulation and/or sensing apparatus. Such electrical connections may be made by using an adaptor of a form having
25 insulated lead wires at a first end for connection to the terminals $60_1 - 60_x$ and ring electrodes, similar to a depth electrode, at a second end. Alternatively, a connector of the suitable for connecting to a substantially flat ribbon cable may be used for making electrical connections to the terminals $68_1 - 68_x$.

30 Also shown in the embodiment of Figure 3 is an interconnecting member 72 which mechanically and electrically interconnects the conductors $60_1 - 60_x$ in order to facilitate handling of the layer 20'' during assembly. Once the layer 20'' is positioned

between the first and second insulating layers 14, 18 and such layers are secured together, the interconnecting member 72 is removed in order to electrically and mechanically isolate the contacts from one another.

5 The dimensions of the contacts 24a - 24x and conductors 28a - 28x may be readily varied to suit a particular application. In the illustrative embodiment, each of the contacts 24a - 24x has a diameter on the order of 0.125 inches and each of the conductors 28a - 28x has a thickness on the order of 0.0005 - 0.0020 inches.

10 Figures 2 and 3 are intended to illustrate some of the possible patterns of contacts 24a - 24x of the patterned metal layer 20 (Figure 1) and arrangements of providing electrical interconnection to conductors 28a - 28x electrically connected to the respective contacts 24a - 24x. It will be appreciated by those of ordinary skill in the art that the number of contacts, their dimensions, arrangement, and the manner of
15 electrically connecting to the contacts via conductors extending from the contacts can be varied to suit a particular application.

 Referring to Figure 4, an alternative method of fabricating the flexible printed circuit patterned metal layer 20 includes using the first flexible insulating layer 14 as a substrate over which the electrode 10 is formed. A layer of metal 84 is deposited
20 over the layer 14 by any one of various conventional techniques, including chemical vapor deposition (CVD) and sputtering. The metal layer 84 is processed to provide the patterned metal layer 20 and may comprise various conductive materials. Suitable conductive materials for providing the metal layer 80 include platinum, stainless steel,
25 copper, aluminum, conductive elastomers, such as copper doped silicone, and conductive polymers. Platinum is often preferred due to its compatibility with magnetic resonance imaging (MRI) technology. Since the metal layer 84 provides the patterned metal layer 20, its thickness is dictated by the desired thickness of the layer 20 and in particular, of the contacts 24a - 24x (Figure 1) and conductors 28a - 28x.
30 The contact thickness, diameter and material will affect its resistance and the overall thickness of the electrode. In the illustrative embodiment, the metal layer 84 has a thickness on the order of between 30 and 40 mils, but can be as thin as 0.5 mils.

Referring also to Figure 5, a layer of photoresist 88 is deposited over the metal layer 84. Conventional photolithographic techniques are used pattern the photoresist layer 88 in order to provide photoresist portions 90 over locations of the metal layer 84 at which contacts 24a - 24x and conductors 28a - 28x are desired and to provide apertures 92 to expose portions of the metal layer 84 where neither contacts nor conductors are to be provided.

The structure of Figure 5 is etched, such as with reactive ion, or chemical etching, to remove the portions of the metal layer 84 exposed through apertures 92 in the patterned photoresist layer 88 and the photoresist is removed. The result is the structure of Figure 6 which includes metal regions providing the contacts 24a - 24x and the conductors 28a - 28x integrally formed with and extending from the respective contacts 24a - 24x.

Thereafter, the second insulating layer 18 is deposited over portions of the patterned metal layer 20 and first insulating layer 14 to provide the resulting structure of Figure 7. In particular, the second insulating layer 18 covers the conductors 28a - 28x and exposed portions of the first insulating layer 14, but does not cover the contacts 24a - 24x. The second insulating layer 18 may be deposited with precise dies or fixtures to overlap a portion of the contacts 24a - 24x, for example, if it is desired to tailor the exposed contact surface area. However, such overlap is not necessary to maintain the contacts 24a - 24x in place since the patterned metal layer 20 adheres to the first insulating layer 14 due to the deposition process.

It will be appreciated by those of ordinary skill in the art that the particular steps and sequence of steps described above in connection with Figures 4 - 7 can be varied in many ways to provide the flexible printed patterned metal layer 20 of Figure 1.

In view of the printed circuit techniques used to provide the patterned metal layer 20, it will be apparent to those of ordinary skill in the art that various electronic features can be provided in, and integrally formed with, the patterned metal layer. That is, electrical components can be embedded therein. As one example, a strain

gauge may be formed as an element of the patterned metal layer, simply by providing a conductor thereon that has a resistance that changes when the conductor is bent. The conductor can be suspended from the first and second insulating layers, such as with the use of an adhesive, in order to permit a middle portion of the conductor to bend.

5 Such a strain gauge would be a useful addition to the implantable medical electrode 10, for example in order to monitor intracranial pressure.

Another feature that may be provided in the patterned metal layer 20 is a temperature sensor. Such a temperature sensor is formed by joining two conductors having dissimilar conductive characteristics (e.g., one copper conductor and one stainless steel conductor). At given temperatures, a proportional potential is developed between the two dissimilar conductors.

10

Having described the preferred embodiments of the invention, it will now become apparent to one of ordinary skill in the art that other embodiments incorporating their concepts may be used. It is felt therefore that these embodiments should not be limited to disclosed embodiments but rather should be limited only by the spirit and scope of the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

15

20 What is claimed is:

1 1. An implantable medical electrode comprising:

2 a first insulating layer;

3 a patterned metal layer disposed over the first insulating layer, the patterned
4 metal layer comprising at least one contact and at least one conductor connected to and
5 extending from the contact; and

6 a second insulating layer having at least one aperture therethrough, said second
7 insulating layer disposed over the patterned metal layer with the at least one aperture
8 aligned with the at least one contact so as to expose a first portion of the contact and
9 cover a second portion of the contact.

1 2. The electrode of claim 1 wherein the first and second insulating layers are
2 comprised of a material selected from the group consisting of polymers.

1 3. The electrode of claim 1 further comprising an adhesive disposed between the
2 first and second insulating layers.

1 4. The electrode of claim 1 wherein the patterned metal layer comprises a plurality
2 of contacts and a plurality of conductors, each of the conductors being connected to and
3 extending from a corresponding one of the plurality of contacts, and wherein the second
4 insulating layer has a plurality of apertures therethrough, each one of the plurality of
5 apertures being aligned with a corresponding one of the plurality of contacts so as to
6 expose a first portion of the respective contact and cover a second portion of the
7 respective contact.

1 5. The electrode of claim 1 wherein each of the first and second insulating layers
2 is flexible in bending.

1 6. A method of fabricating an implantable medical electrode, comprising the steps
2 of:
3 providing a first insulating layer;
4 providing a metal pattern comprising at least one contact and at least one
5 conductor electrically connected to and extending from the contact;
6 placing the metal pattern over the first insulating layer;
7 providing a second insulating layer having at least one aperture therethrough;
8 and
9 covering the metal pattern with the second insulating layer so that the at least
10 one aperture in the second insulating layer is aligned with the at least one contact to
11 expose at least a portion of the contact.

1 7. The method of claim 6 wherein the covering step comprises the step of using
2 an adhesive to cause the second insulating layer to adhere to the first insulating layer.

1 8. The method of claim 6 wherein the step of placing the metal pattern over the
2 first insulating layer comprises the step of using an adhesive to cause the metal pattern
3 to adhere to the first insulating layer.

1 9. The method of claim 6 wherein each of the steps of providing the first insulating
2 layer and the providing the second insulating layer comprises the step of selecting the
3 material of the respective insulating layer from the group consisting of polymers.

1 10. The method of claim 6 wherein the step of providing a metal pattern comprises
2 the steps of:
3 providing a substrate;
4 depositing a layer of metal over the substrate; and
5 etching the metal layer to provide the metal pattern.

1 11. The method of claim 6 wherein the step of providing a metal pattern comprises
2 the step of selecting the material for the metal layer from the group consisting of
3 copper, aluminum, platinum, stainless steel, conductive elastomer, and conductive
4 polymer.

1 12. The method of claim 6 wherein the second insulating layer is aligned with the
2 at least one contact so as to expose a first portion of the contact and cover a second
3 portion of the contact.

1 13. The method of claim 6 wherein the step of providing a first insulating layer
2 comprises the step of providing the first insulating layer to be flexible in bending and
3 the step of providing a second insulating layer comprises the step of providing the
4 second insulating layer to be flexible in bending.

1 14. A method of fabricating an implantable medical electrode, comprising the steps
2 of:

3 providing a first flexible insulating layer;

4 depositing a metal layer over the first flexible insulating layer;

5 patterning the metal layer to provide a patterned metal layer comprising at least
6 one contact and at least one conductor electrically connected to and extending from the
7 contact;

8 providing a second flexible insulating layer having at least one aperture
9 therethrough; and

10 covering the patterned metal layer with the second flexible insulating layer so
11 that the at least one aperture in the second insulating layer is aligned with the at least
12 one contact of the patterned metal layer so as to expose at least a portion of the contact.

1 15. The method of claim 14 wherein each of the steps of providing the first
2 insulating layer and the providing the second insulating layer comprises the step of
3 selecting the material of the respective insulating layer from the group consisting of
polymers.

1 16. The method of claim 14 wherein the step of patterning the metal layer to
2 provide the patterned metal layer comprises the steps of:

3 depositing a layer of photoresist over the metal layer;

4 patterning the photoresist layer;

5 etching the patterned photoresist layer to provide the patterned metal layer; and

6 removing the patterned photoresist layer.

1 17. The method of claim 14 wherein the step of depositing a metal layer comprises
2 the step of selecting the material of the metal layer from the group consisting of copper,
3 aluminum, platinum, stainless steel, conductive elastomer, and conductive polymer.

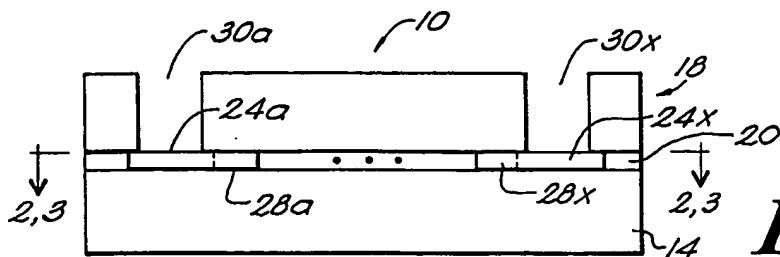


FIG. 1

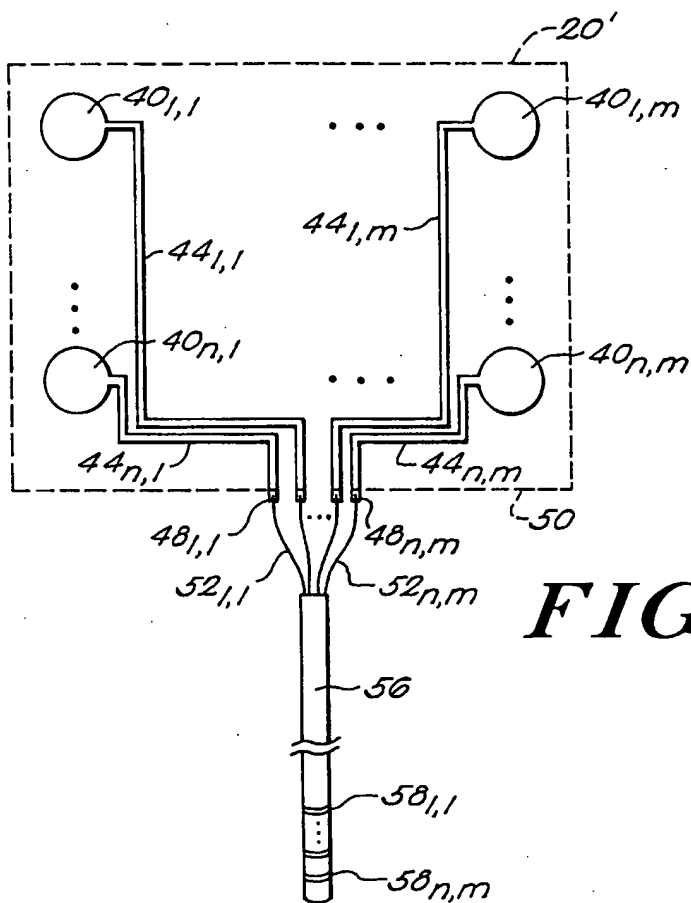


FIG. 2

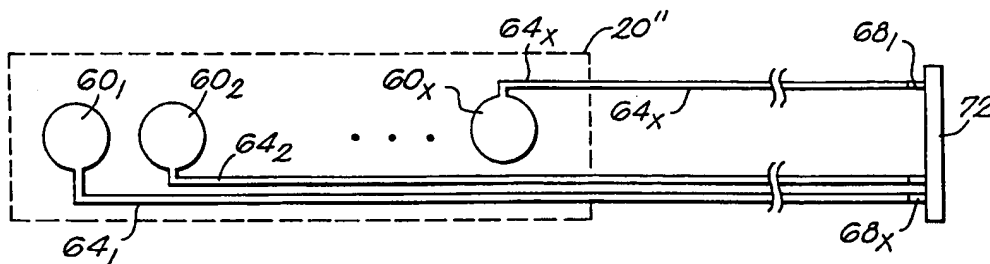


FIG. 3

2 / 2

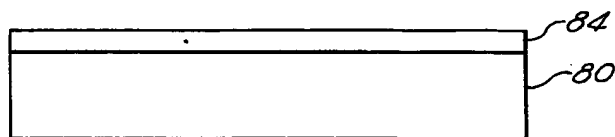


FIG. 4

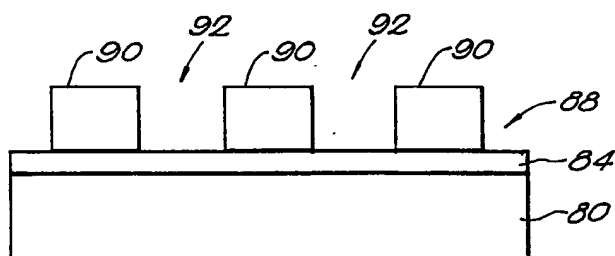


FIG. 5

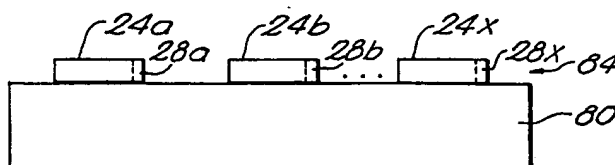


FIG. 6

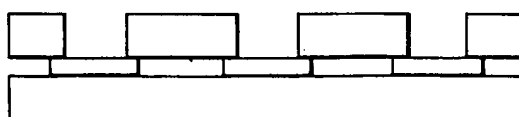


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/05879

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 903 702 A (PUTZ DAVID A) 27 February 1990	1-9, 11-13 14-17
A	see column 3, line 24-39 see column 4, line 29-45 see column 5, line 20-35 ---	
X	WO 93 20887 A (UNIV CASE WESTERN RESERVE) 28 October 1993	1,2,4-6, 9,11-15, 17 10,16
A	see page 3, line 1-16 see page 3, line 36 - page 4, line 5 see page 7, line 5-32 --- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance
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"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

Date of the actual completion of the international search

24 June 1999

Date of mailing of the international search report

06/07/1999

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Grossmann, C.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/05879

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	PECKERAR M ET AL: "PASSIVE MICROELECTRODE ARRAYS FOR RECORDING OF NEURAL SIGNALS: A SIMPLIFIED FABRICATION PROCESS" REVIEW OF SCIENTIFIC INSTRUMENTS, vol. 62, no. 9, 1 September 1991, pages 2276-2280, XP000262874	1,2,4,6, 9,10,12
A	see the whole document	11,14-17
X	ANDERSON D J ET AL: "BATCH-FABRICATED THIN-FILM ELECTRODES FOR STIMULATION OF THE CENTRAL AUDITORY SYSTEM" IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, vol. 36, no. 7, 1 July 1989, pages 693-703, XP000037461	1,4,6, 10,12
A	see the whole document	2,9,11, 14-17
A	EP 0 585 933 A (MATSUSHITA ELECTRIC IND CO LTD) 9 March 1994 see column 2, line 42 - column 3, line 28 see column 6, line 28 - column 7, line 5	1,2,4-6, 9-17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/05879

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4903702	A	27-02-1990	NONE	
WO 9320887	A	28-10-1993	US 5324322 A AU 4108693 A	28-06-1994 18-11-1993
EP 0585933	A	09-03-1994	JP 6296595 A JP 6078889 A US 5810725 A	25-10-1994 22-03-1994 22-09-1998